510(k) Summary for
Narrow Band, Near-IR Energy, Pain Therapy Devices

1. SPONSOR

FEB 2 5 2005

Life Without Pain, LLC
1600 S. Federal Highway
Suite 350
Pompano Beach, FL 33062

Contact Person: Irwin Newman, President
Telephone: 954-786-0007

Submission Date: February 23, 2005

2. DEVICE NAME

The Narrow Band, Near-IR Energy, Pain Therapy Devices (Models: BioBeam™ 660, BioBeam™ 940, MedLight™ 1630, and MedLight™ 2630) are over-the-counter devices that use light-emitting diodes (LEDs) in the near-IR spectrum for the relief of pain. Pain-relief devices have been classified as Class II devices under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Infrared Lamp	ILY	890.5500	Physical Therapy

3. PREDICATE DEVICES

Narrow Band, Near-IR Energy, Pain Therapy Devices are substantially equivalent to the Quantum WARP 10 Light Delivery System, 510(k) No. K032229, Light Force Therapy's SuperNova, 510(k) No. K022888, and Diomedics' Pain-X-2000, 510(k) No. K982546.

4. DEVICE DESCRIPTION

The Narrow Band, Near-IR Energy, Pain Therapy Devices use LEDs to generate heat that alleviates pain. Two ranges are employed: 630 nm and 940 nm, depending on the product model, as well as a choice of continuous wave and

pulse wave (BioBeam™ models only) modes. The units are available in hand-held or mounted configurations.

5. INTENDED USE

Narrow Band, Near-IR Energy, Pain Therapy Devices emit energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Narrow Band, Near-IR Energy, Pain Therapy Devices are similar to the predicate devices in terms of principle of operation, wavelength, waveform, energy, recommended treatment time, target size.

7 TESTING

Narrow Band, Near-IR Energy, Pain Therapy Devices have been tested for electrical safety and electromagnetic compatibility. Materials that may come in contact with the treatment site have been tested for biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2005

Life Without Pain, LLC
c/o Mr. Daniel J. Dillon
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K042813
Trade/Device Name: Narrow Band, Near-IR Energy, Pain Therapy Devices
(Models: BioBeam™ 660, BioBeam™ 940, MedLight™ 1630, and MedLight™ 2630)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: February 14, 2005
Received: February 15, 2005

Dear Mr. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K042813**

Device Name: Narrow Band, Near-IR Energy, Pain Therapy Devices (Models: BioBeam™ 660, BioBeam™ 940, MedLight™ 1630, and MedLight™ 2630)

Indications for Use:

Narrow Band, Near-IR Energy, Pain Therapy Devices emit energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

Prescription Use _____ AND/OR Over-the-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042813